K081758
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5. 510(K) SUMMARY

Submitter:
DePuy Spine, Inc.
325 Paramount Drive
Raynham, MA 02767

SEP - 3 2008

Contact Person:
Hande Tufan
Sr. Regulatory Affairs Associate
Voice: (508) 828-3065
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Date Prepared: June 19, 2008

Device Class: Class II

HEALOS® F_X Device Classification Name: Resorbable calcium salt bone void filler
§888.3045

HEALOS® F_X Graft Mixing and Delivery System Classification Name: Piston Syringe
§880.5860

Classification Panel: Orthopedic

FDA Panel Number: 87

Product Code(s): MQV and FMF

Proprietary Name:
HEALOS® Fx Injectable Bone Graft Replacement
HEALOS® Fx Graft Mixing and Delivery System

Predicate Devices:
(Material)
HEALOS® Bone Graft Substitute (K012751 and K043308)
HEALOS® Fx Bone Graft Substitute (K062495)

(Mixing/Delivery device)
HEALOS® Fx Graft Mixing and Delivery System (K062495)
Symphony® Graft Delivery System (K003286)
Harvest® Graft Delivery System (K043261)
Imbibe® II Syringe (K030208)

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Device Description:

HEALOS Fx Injectable Bone Graft Replacement is a mineralized collagen matrix processed into lyophilized fibrous material for surgical implantation. The principal components of the HEALOS Fx Injectable Bone Graft Replacement are Type I bovine collagen and hydroxyapatite. HEALOS Fx is approximately 20-30% mineral by weight.

The HEALOS Fx Graft Mixing and Delivery System is designed to facilitate the mixing of autogenous bone marrow aspirate with the HEALOS Fx material and to deliver this bone graft mixture into the surgical site. Included in the kit are two chambers: a mixing chamber and a delivery chamber.

Intended Use:

HEALOS® Fx Injectable Bone Graft Replacement ("HEALOS Fx"), combined with autogenous bone marrow is intended for use in filling bony voids or gaps of the skeletal system (i.e., the extremities, spine, and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. The product provides a bone void filler that is resorbed and remodeled into new bone as part of the natural healing process.

The HEALOS® Fx Graft Mixing and Delivery System is indicated for the mixing and delivery of HEALOS Fx Injectable Bone Graft Replacement to a surgical site.

Materials:

The principal components of HEALOS Fx Injectable Bone Graft Replacement are Type I bovine collagen and hydroxyapatite.

The principal components of the HEALOS Fx Graft Mixing and Delivery System are copolymer and plastic materials.

Performance Data:

No performance standards have been established for this type of device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 3 2008

Dupuy Spine, Inc.
% Mr. Hande Tufan
Senior Regulatory Affairs Associate
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K081758
Trade/Device Name: HEALOS® Fx Injectable Bone Graft Replacement
HEALOS® Fx Graft Mixing and Delivery System
Regulation Number: 21 CFR 888.3045
Regulation Names: Resorbable calcium salt bone void filler device.
Regulatory Class: II
Product Code: MQV, FMF
Dated: June 19, 2008
Received: June 20, 2008

Dear Mr. Tufan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K081758

Device Name: HEALOS® Fx Injectable Bone Graft Replacement
HEALOS® Fx Graft Mixing and Delivery System

HEALOS® Fx Injectable Bone Graft Replacement Indications For Use:

HEALOS® Fx Injectable Bone Graft Replacement ("HEALOS Fx"), combined with autogenous bone marrow, is intended for use in filling bony voids or gaps of the skeletal system (i.e., the extremities, spine, and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. HEALOS Fx is a bone graft substitute that is resorbed and remodeled into new bone as part of the natural healing process.

HEALOS® Fx Graft Mixing and Delivery System Indications for Use:

The HEALOS® Fx Graft Mixing and Delivery System is indicated for the mixing and delivery of HEALOS® Fx Injectable Bone Graft Replacement to a surgical site.

Prescription Use ___X___ AND/OR Over-The-Counter Use ___ ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081758